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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,653	09/21/2006	Vlasios Andronis	PB60811	2987

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EXAMINER	
MANOHAR, MANU M	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,653	ANDRONIS ET AL.	
	Examiner	Art Unit	
	MANU M. MANOHAR	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/05/2007, 11/10/2006, 09/21/2006.*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The status of the Claims

Claims 1-32 are pending in the application.

Priority

The application is with a filing date of September 21, 2005. This application is a 371 of PCT/US05/10350 with filing date of March 28, 2005 which claims the benefit of application 60/557,571 with the filing date of March 30, 2004 and examiner acknowledge the filing date. For this application the priority date is March 30, 2004.

Information Disclosure Statement

An information disclosure statement was filed on November 11, 2006 but the Foreign Patent Documents fail to comply with 37 CFR 1.98(a) (3). A reference is not in the English language, and a concise explanation of its relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, is not provided. It has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894);

In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Application No 12/088661. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-22 of U.S. Patent Application 12/088661 embraces the instant claims 1-32. The instant claims 1-32 encompasses the preparation and composition of the spray dried pharmaceutical composition comprising talnetant and other excipients like surfactant, carrier. The claims 1-22 in the pending application (12/088661) also encompasses the preparation and composition of the spray dried pharmaceutical composition comprising talnetant and other excipients like surfactant, carrier however the pending application 12/088661 also states the composition comprising the excipient povidone. However adding additional or different surfactant or carrier agents for a pharmaceutical composition is a part of normal routine optimization procedure and hence it would be obvious to one of the ordinary skill in the art to modify the composition as taught by the pending application 12/088661 based on the requirement.

Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Application No 12/088647. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-29 of U.S. Patent Application 12/088647 embraces the instant claims 1-32

The instant claims 1-32 encompasses the preparation and composition of the spray dried pharmaceutical composition comprising talnetant and other excipients like surfactant, carrier. The claims 1-29 in the application (12/088647) also encompasses the preparation and composition of the spray dried pharmaceutical composition comprising talnetant and other excipients like surfactant, carrier however the pending application 12/088647 also states the composition comprising the excipient povidone and erythritol. However adding additional or different surfactant or carrier agents like povidone and erythritol for a pharmaceutical composition is a part of normal routine optimization procedure and hence it would be obvious to one of the ordinary skill in the art to modify the composition as taught by the pending application 12/088647 based on the requirement.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farina et al (International Patent Application WO/95/32948) in view of Pace et al (US Patent Application US 2002/0056206).

Farina et al discloses compounds like talnetant [(s)-(-)-N-(alpha-ethylbenzyl)-3-hydroxy-2-phenylquinoline-4-carboxamide] as claimed in the instant claim 1 and 19 as useful pharmaceutical agents, NK3 receptor antagonist, for treating several disorders like pulmonary, CNS and neurodegenerative disorders (Abstract and page 1 line 35-page 2 line 24).

Farina et al does not teach the process of the preparation of the pharmaceutical composition with the bulking agents or excipients like surfactant and carriers. Pace et al teaches the process of preparation of spray dried pharmaceuticals with different bulking agents. Pace et al teaches the preparation of spray dried pharmaceutical composition in different dosage forms including oral form like tablet (abstract) as in the instant claims 1, 19, 30, 31 and 32, with ionic surfactant (page 12 column 1 line 1-4), soluble carrier (page 26 claim 39), with various particle sizes (claims 11, 12 and 13). Pace et al teaches the pharmaceutical compositions with different particle sizes including the particle size 0.1 to 2.0 micrometer (claims 11, 12 and 13) as in the instant claims 1 and 19. Pace et al also describes the wet milling process of the preparation of the pharmaceuticals in an aqueous based medium (Page 24 claim 1, page 16 paragraph

[165]) as claimed in the instant claims 1 and 2 and the preparation can be in the dispersion form (page 16, paragraph [0167]). In addition Pace et al teaches the active ingredient in the composition can be from 1 to 90% (page 19, column 2 paragraph [0199]) which include the ranges as claimed in the instant claims 3 and 4. Moreover Pace et al also teaches the composition with ionic surfactant, sodium lauryl sulfate as claimed in claims 1, 5, 6, 7, 19, 20, 21 and 22 (page 12 column 1 line 1-4). Pace et al teaches the surfactant concentration can be 0.5 to 50% (page 19 paragraph 195) which include the concentration as claimed in the instant claims 8 and 23. Although Pace et al do not specifically teaches the concentration like 0.05% or 0.001 to 0.1 moles it is part of routine optimization of this art unless teachings are present to the contrary. Pace et al teaches the preparation of pharmaceutical composition with carrier such as mannitol and lactose (page 26 claim 39) as claimed in the instant claims 11, 12, 13, 24, 25 and 26. Pace et al also teaches the concentration of the carrier can range from 0.1 to 90% (page 19, paragraph [0199] stated as bulking agent) as which include the range claimed in the instant claims 14 and 15. Pace et al teaches the preparation of pharmaceutical compositions with anti-agglomeration agents such as carboxymethyl cellulose, PVP, methylhydorxy ethyl cellulose in a concentration ranges from about 0.1% to 20% (page 22 paragraph [0229]) as claimed in the instant claims 16, 17, 18, 28 and 29)

Claims 19-32 are the product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. The process of manufacture recited in claim 1 is known to those of ordinary skill in the art and there is no indication that the process described in claim 1 results in a pharmaceutical composition that is patentably distinct from the compositions disclosed in the prior art.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to modify the method of preparation of the composition with talnetant as taught by Farina et al with the teaching of Pace et al as spray dried pharmaceuticals. Several investigations are aimed to develop effective pharmaceutical composition including spray dried pharmaceuticals with various concentration of active ingredients and other components like carriers. Hence one of the ordinary skills in the art would be motivated to develop effective spray dried pharmaceuticals. Given the teachings of Farina et al, in view of Pace et al, one of ordinary skill in the art would have a reasonable expectation of success to formulate the pharmaceutical composition of the instant claims with the amount of active ingredient present. This renders the claims of the instant application obvious to one of ordinary skill in the art at the time of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is

(571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-270-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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